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INSTITUTE OF RADIOLOGY
WASHINGTON UNIVERSITY
MEDICAL CENTER

RADIATION ONCOLOGY CENTER
Washington University
24-00063-10

August 8, 1994

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

RE: NRC Inspection Report No. 030-15101/94001 (DRSS)

Enclosed is our institution's response to your letter dated July 11, 1994 that reported the results of the special safety inspection conducted by NRC staff in regards to a Cobalt-60 teletherapy misadministration at our facility. In the violation notice, there is acknowledgment of the immediate and follow-up actions taken by our facility in regard to the event and the apparent violations noted at that time. Details of these actions were distributed at the enforcement meeting that took place on June 29, 1994.

We do not contest any of the violations. We reiterate some of the actions already taken that pertain to the violations and note further actions taken since the enforcement meeting. These actions and other long term actions address the event, but more importantly, are intended to diminish weaknesses in our program and avoid recurrence of any such events.

Sincerely,

Eric E. Klein

Eric E. Klein, M.S.
Deputy Radiation Safety Officer
Radiation Oncology Center

John Eichling

John Eichling, Ph.D.
Radiation Safety Officer
Washington University

EEK/JE:clz

Enclosures

CC: John B. Martin, Regional Administrator, Region III,
U.S. Nuclear Regulatory Commission
Walter Davis, Assistant Dean for Facilities and Chief Facilities Officer for
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I. Reply to a Notice of Violation (and Inspection Report No. 0303-15101/94001)

Violation A: 10 CFR 35.32 (a) (1) requires, in part, that each licensee establish and maintain a written quality management program which must include written policies and procedures to meet the objective that, prior to the administration, a written directive is prepared for any teletherapy radiation dose. The licensee's quality management program, dated January 27, 1992, Item 17.2, requires, in part, that oral directives and revisions to written directives shall be made as provided in Regulatory Guide 8.33 Section 5. Regulatory Guide 8.33, Section 5, states, in part, that a written revision to an existing written directive may be made for any therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the next teletherapy fractional dose. Contrary to the above, on April 22, 1994, the licensee failed to make a written revision to a written directive prior to administering a revised teletherapy dose to a patient.

Response

Prior to the NRC inspection, we had already identified the lack of timely change to the written directive as a Recordable Event. We followed our QMP procedures for notification, corrections, and re-education. We met with the entire staff and re-emphasized two important points: (1) Any change to the planned treatment must be accompanied by a change in the written directive, if any of the parameters are changed, including treatment site. (2) The treating therapists have the responsibility to question the physician as to whether a change in the written directive is required, before treating the patient. They have been instructed to question any technique change, no matter how subtle, as to whether a written directive change is required. This has made a positive improvement to our program.

Violation B: 10 CFR 35.25 (a) (2) required, in part, that a licensee that permits the use of byproduct material under the supervision of an authorized user shall require the supervised individual to follow the written quality management procedures established by the licensee. The licensee's quality management program dated January 27, 1992, Item 17.4, requires, in part, that prior to administering each teletherapy dose, the therapy technologist must review the written prescription to verify that the specific details of the administration are in accordance with the written directive and plan of treatment. In particular, the treatment site and the dose per fraction will be confirmed by the person administering the teletherapy treatment. Contrary to the above, on April 22, 1994, the therapy technologist, an individual under the supervision of the licensee's authorized users, failed to review the written prescription and failed to verify that the details of the administration of the verbally revised dose were in accordance with the written directive and plan of treatment. In addition, the therapy technologist failed to review written directives and the plans of treatment prior to administering each teletherapy dose on a routine basis.

Response

The inspection did identify that particular therapists were not consistently reviewing the written directive prior to treatment. We conducted QMP in-services on the following dates (4/22/94, 5/20/94, 6/20/94) that reminded the therapists of their duty to review the written directive before every treatment. Other managerial changes that have been made include the following: (1) We have implemented a policy requiring semi-annual review sessions regarding our teletherapy QMP. These review sessions will be taught by either the clinical physicist or the therapists supervisors and will reiterate our teletherapy QMP policies and procedures, and answer any questions. 2) In our efforts to evaluate and examine therapists and their supervisors, we have begun to ensure they have complete understanding of QMP. Our process includes continuing education programs relevant to QMP and subsequent review of the material on a regular basis; exams for verification of comprehension; incorporation of QMP performance and to the annual employee performance evaluation for therapy supervisors; and development of clear standards and expectations relevant to the therapist supervisor's active role in management of the QMP program.

(3) Management has agreed to limit the number of therapists that will be assigned to treat on the Cobalt unit. This will avoid any confusion the therapists may have in rotating from an isocentric medical accelerator to a stand mounted Cobalt-60 teletherapy unit.

Violation C: 10 CFR 35.25 (a) (2) requires, in part, that a licensee that permits the use of byproduct material under the supervision of an authorized user shall require the supervised individual to follow the written quality management procedures established by the licensee. The licensee's quality management procedure, dated January 27, 1992, Item 17.1, requires, in part, that prior to administering a Co-60 teletherapy treatment the therapy technologist shall verify the patient's identity by at least two of the specified methods. Contrary to the above, as of May 3, 1994, the licensee's radiation therapists, individuals under the supervision of the licensee's authorized users, did not follow the written quality management procedures established by the licensee in that on of the methods used to identify patients ("name answered to") was not one of the methods specified in the quality management procedures for patient identification.

Response

The inspection identified that one of our common methods for identifying the patient was passive. We have instructed the therapist that "name answered to" was not an acceptable method of patient identification. Instead, we have implemented a sign at the Co-60 teletherapy unit that the therapist will read to the patient prior to each treatment. The sign reads" "For your safety, federal law requires that you identify yourself to the radiation therapist by stating your full name prior to each treatment." We are also using the face photograph in the treatment chart as a second method for patient identification. In cases where one of these methods are not available, the patient will be identified by ID bracelet, ID card, signature, or by relative or guardian of the patient. In all cases, the patient will be identified by two independent methods.

Violation D: 10 CFR 35.32 (a) (1) requires, in part, that each licensee establish and maintain a written quality management program which must include written policies and procedures to meet the objective that, prior to the administration, a written directive is prepared for any teletherapy radiation dose. 10 CFR 35.2 defines a written directive for teletherapy as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of the radiation which contains the total dose, dose per fraction, treatment site, and overall treatment period. The licensee submitted a quality management program (QMP) and a written certification to the NRC on January 23, 1992. The plan was implemented on January 27, 1993. Contrary to the above, as of May 3, 1994, the licensee's written quality management program failed to include written procedures to meet the objective that a written directive for a teletherapy dose must include the overall treatment period. As a result, written directives did not contain the overall treatment period.

Response

The inspection identified that our written directives did not explicitly include the overall treatment period. As we are in process of updating our treatment charts, the overall treatment period (weeks) will be written in the written directive section. In the interim, the physicians will include the overall treatment time period (weeks) as part of the written directive on our current treatment forms.

In summary, we will have these supervisory and educational policies and procedures in place by August 9, 1994. Any desired documentation pertinent to our actions can be forwarded if desired, and will be available for any future inspections.